

REMARKS

I. Status of the Application

Claims 186-194, 197, and 199-203 are pending following Applicants Request for Continued Examination and amendments made herein. Applicants have amended Claims 186-190 and 199, and have added new Claims 200-203. Support for these amendments and for the new claims can be found throughout the Specification and claims as filed, for example, at page 4, lines 23-24, page 7, lines 7-20, page 20 line 14 through page 27 line 6, and in currently cancelled Claim 195, among other places. No new matter has been added.

II. The Claims Are Definite

The Examiner rejected Claims 186-199 under 35 U.S.C. § 112, first paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention (Office Action at page 5). Applicants respectfully disagree.

Applicants contend that the claims are definite. Applicants respectfully submit that the Specification clearly defines what the term "surface of a human" means in the context of the claims. For example, the Specification describes the surface of a human as both the outermost boundaries (e.g., skin, mucosal cells and tissues and hair) as well as the inner membranes (e.g., digestive tract, vascular tissues) that are capable of being contacted with a composition of the invention (See, e.g., Specification at page 17, lines 28-29; page 18, lines 1-2 and 25-30; and page 19, lines 1-3, among other places).

Thus, Applicants respectfully submit that the Claims are definite and request that the Examiner withdraw the rejection under 35 U.S.C. § 112.

III. The Claims are Not Anticipated

The Examiner rejected Claims 186-188, 191, 193, 194 and 197-199 under 35 U.S.C. 102(b) as allegedly being anticipated by Asculai et al. (U.S. Pat. No. 4,020,183). Applicants respectfully disagree.

Nonetheless, without acquiescing to the Examiner's arguments and in order to expedite the patent application process and without waiving the right to prosecute the amended, cancelled, or similar claims in the future, Applicants herein amend Claim 186 and cancel Claims 195-196,

and 198. Claim 186 as amended recites a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of a human to a nanoemulsion composition, or a dilution thereof, the nanoemulsion comprising 1) a discontinuous oil phase; 2) an aqueous phase; 3) 3-15% by volume ethanol; and 4) 3-15% by volume surfactant; and 5) a halogen-containing compound.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."¹ Furthermore, the law requires that the single prior art reference provide an *enabling* disclosure of the claimed invention.² Importantly, a prior art reference provides an enabling disclosure only "if the public was in possession of the claimed invention before the date of invention."³

Applicants respectfully submit that Asculai et al. does not teach or possess all of the elements of Claim 186, or claims dependent thereon. Similarly, Applicants submit that Asculai et al. does not teach or possess all of the elements of new Claims 200 and 202, or claims dependent thereon. In particular, Asculai et al. do not teach or disclose a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of a human to a nanoemulsion composition, or a dilution thereof, wherein the nanoemulsion is defined by the claim limitations present in independent Claims 186, 200, or 202.

Moreover, Asculai et al. do not provide information regarding whether or not a method of topically treating a human having a *Herpes simplex I* virus infection using a composition as claimed in Claim 186, Claim 200, or Claim 202 would be successful. That is, because Asculai et al. do not teach or disclose a composition as claimed in the present invention, one of ordinary skill in the art could not know, prior to the disclosure of the present invention, whether such compositions could be used in a method of topically treating a human having a *Herpes simplex I* virus infection.

Accordingly, because Asculai et al. do not teach, disclose or enable the presently claimed invention, Applicants respectfully request that the Examiner withdraw the rejection made under 35 U.S.C. § 102.

¹ *Verdegaal Bros. v Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

² See, e.g., MPEP 2121.01.

³ See, e.g., MPEP 2121.01.

IV. The Claims are Not Obvious

The Examiner rejected Claims 186-188, 191, 193, 194 and 197-199 under 35 U.S.C. §103(a) over Asculai et al. (U.S. Pat. No. 4,020,183); and Claims 186-199 under 35 U.S.C. § 103(a) as being unpatentable over Libin (U.S. Pat. No. 5,855,872) in view of Stroud et al. (U.S. Pat. No. 6,231,837). Applicants respectfully disagree.

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness.⁴ A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.⁵ An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art.⁶

The test for *prima facie* obviousness is consistent with legal principles enunciated in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). The Federal Circuit summarized the Supreme Court's holding in *KSR* that "While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test, the Court acknowledged the importance of identifying 'a *reason* that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Takeda Chem. Indus., Ltd. v. Alphapharma Pty., Ltd.*, 06-1329, slip op. (Fed. Cir. June 28, 2007), at 13-14 (quoting *KSR*, 127 S. Ct. at 1731) (emphasis added). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. *KSR*, 127 S. Ct. at 1731. The *KSR* Court upheld the secondary considerations of non-obviousness, noting that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* Additionally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. 2143.

Applicants respectfully submit that the cited references, individually or combined, do not teach or suggest each element of the claimed invention.

A) Asculai et al. (U.S. Pat. No. 4,020,183)

As described above, Asculai et al. does not teach or suggest a method of topically treating

⁴ See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

⁵ *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993).

⁶ *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

a human having a *Herpes simplex I* virus infection, comprising exposing a surface of a human to a nanoemulsion composition, or a dilution thereof, the nanoemulsion comprising 1) a discontinuous oil phase; 2) an aqueous phase; 3) 3-15% by volume ethanol; and 4) 3-15% by volume surfactant; and 5) a halogen-containing compound (e.g., as recited in Claim 186). Similarly, Asculai et al. does not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition comprising: 1) 50-80% by volume oil; 2) distilled water; 3) 3-15% by volume ethanol; 4) 3-15% by volume surfactant; and 5) cetylpyridinium chloride (e.g., as recited in Claim 200); nor a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition comprising: 1) 3-15% by volume surfactant; 2) 3-15% by volume ethanol; 3) 50-80% by volume oil; 4) cetylpyridinium chloride; 5) distilled water; and 6) ethylenediaminetetraacetic acid (e.g., as recited in Claim 202).

Thus, Asculai et al. fails to teach or suggest all the claim limitations. Applicants respectfully submit that on this basis alone the rejection should be withdrawn.

Asculai et al. relates to inactivation of herpes virus “by treating the infected area with a nonionic surface active agent.”⁷ Asculai et al. recite

“Nonionic surface active agents, in contrast to cationic, anionic and ampholytic surface active agents, contain no ionizable groups and have no surface charge. They depend upon their entire molecule for surface activity. Almost any hydrophobic compound which has in its structure a carboxy, hydroxy, amido or amino group with a free hydrogen attached to the nitrogen, can be reacted with ethylene oxide to form a nonionic surfactant.”⁸

Asculai et al. then proceed to list an expansive array of various types of surfactants, any one of which could be selected by one of ordinary skill in the art for use for further investigation. Asculai et al. also provide a broad list of pharmaceutically acceptable vehicles that may be used to harbor any one of the various types of surfactants. “The vehicle may be in any suitable form such as a lotion, cream, oil or emulsion, for example.”⁹ Asculai et al. provide a broad array of

⁷ See U.S. Pat. No. 4,020,183, column 1, lines 26-28.

⁸ See U.S. Pat. No. 4,020,183, column 1, lines 29-39.

⁹ See U.S. Pat. No. 4,020,183, column 2, lines 45-47.

different types of vehicles that include polyethylene glycol, mineral oil, petrolatum, propylene glycol and the like.”¹⁰

Asculai et al. never teach or suggest generation of a composition defined by the limitations of the pending claims, nor the use of such a composition in a method of topically treating a human having a *Herpes simplex I* virus infection. In particular, because Asculai et al. teach that non-ionic surfactants are anti-viral, Asculai et al. never teach or suggest combining a non-ionic surfactant in any type of carrier with other reagents that also may possess anti-viral properties (e.g., as claimed in the present invention).

Applicants respectfully submit that in effect the Examiner is attempting to make an obvious to try type argument. That is, because Asculai et al. reference various reagents that could be combined, it would have been obvious to combine them in an effort to produce a method of the claimed invention. However, Applicants respectfully submit that this type of argument is factually and legally unsupportable.

In light of recent Supreme Court and Federal Circuit decisions, a conclusion that the presently claimed invention is prima facie obvious because it is allegedly "obvious to try" is factually and legally unsupportable.

In *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the Supreme Court specifically noted that, in some circumstances, "the fact that a combination was obvious to try ***might*** show that it was obvious under §103." (emphasis added). The Supreme Court's decision specifically referred to circumstances

"When there is ***a design need or market pressure to solve a problem*** and there are ***a finite number of identified, predictable solutions***, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. ***In that instance the fact that a combination was obvious to try might show that it was obvious under §103.***" (emphasis added).

Subsequently, and in view of the unanimous Supreme Court decision in KSR, the Federal Circuit reemphasized that

"[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." KSR, 127 S. Ct. at 1732. In

¹⁰ See U.S. Pat. No. 4,020,183, column 1, lines 47-49.

such circumstances, 'the fact that a combination was obvious to try might show that it was obvious under § 103.' Id."¹¹

However, the Federal Circuit, following the guidance of the Supreme Court, distinguished the circumstances of KSR from those before it in Takeda Chemical.

In Takeda Chemical, the appellant, Alphapharma, argued in a Declaratory Judgment action that a claimed chemical compound was an obvious modification of a previously known compound, the modification requiring the substitution of a homolog in a different ring position.¹² Specifically, and in an attempt to seize upon the Supreme Court's acknowledgment that a combination of elements that are obvious to try might support obviousness under § 103, Alphapharma argued to the Federal Circuit that the claimed compounds would have been obvious because the prior art compound fell within "the object reach of the claim," and the evidence demonstrated that using the techniques of homologation and ring-walking would have been "obvious to try."

The Federal Circuit rejected Alphapharm's arguments and held that in view of KSR, in circumstances in which the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation, the prior art does not provide a predictable solution... Thus, this case fails to present the type of situation contemplated by the [Supreme] Court when it stated that an invention may be deemed obvious if it was "obvious to try." The evidence showed that it was not obvious to try."¹³

Applicants have pointed out that Asculai et al. provide non-ionic surfactants for use, in a pharmaceutically acceptable carrier, in inactivating herpes simplex virus. Applicants have further pointed out that Asculai et al. provide an expansive array of various types of surfactants any one of which could be selected by one of ordinary skill in the art for use in further investigations (e.g., in an effort to determine which ones may or may not possess the ability to inactivate herpes simplex). Additionally, Applicants have also pointed out that Asculai et al. discuss a multiplicity of different types of pharmaceutically acceptable carriers to which a non-ionic surfactant could be added.

Thus, an argument that the cited references render the claimed invention *prima facie* obvious because it might appear obvious to try (e.g., obvious to try to select any one of a number

¹¹ See *Takeda Chemical Industries v. Alphapharm*, No. 06-1329, *slip op.* (Fed. Cir. June 28, 2007), at 15.

¹² Id.

¹³ Id.